

EXHIBIT 1

SETTLEMENT AGREEMENT

This Settlement Agreement (the “Agreement”) is entered into amongst the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS) (collectively, the “United States”), Arriva Medical, LLC (Arriva) and Alere Inc. (Alere) (together, “the Arriva Defendants”), and Relator Gregory M. Goodman (“Relator”) (hereafter, the United States, the Arriva Defendants, and Relator are collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. From 2009 until December 2017, Arriva was a Florida-based mail-order supplier of diabetic testing supplies to, amongst others, beneficiaries of the Medicare program. Arriva was founded in 2009 by David Wallace and Timothy Stocksdales, who, along with other investors, owned Arriva until November 2011. From 2009 until the sale of Arriva to Alere in November 2011, Wallace and Stocksdales operated and managed Arriva. Starting in November 2011, Arriva was a subsidiary of Alere, which oversaw and controlled Arriva’s operations during this period. Arriva and Alere were purchased by Abbott Laboratories (“Abbott”) in October 2017, after the conduct described in Paragraph D below. As of October 2017, Abbott is the parent of Arriva and Alere.

B. On August 1, 2013, Relator filed a *qui tam* action against the Arriva Defendants in the United States District Court for the District of Middle District of Tennessee captioned *United States ex rel. Goodman v. Arriva Medical, LLC, et al.*, No. 3:13-cv-00760, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”). The United States intervened in part in the Civil Action on February 8, 2019 and asserted additional claims. The

United States filed its Complaint-in-intervention on May 14, 2019 and its Amended Complaint-in-intervention on August 1, 2019 (collectively, the “Amended Complaint”). On May 14, 2019, Relator dismissed his non-intervened claims.

C. The United States contends that the Arriva Defendants submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (“Medicare”).

D. As set forth in the Amended Complaint and in this paragraph, the United States contends that it has certain civil claims against the Arriva Defendants because the Arriva Defendants knowingly submitted or caused the submission of false claims on behalf of Arriva customers to Medicare by engaging in the following conduct:

1. From April 1, 2010 through December 31, 2016, the United States contends that the Arriva Defendants, in violation of the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b(b), (1) knowingly and willfully offered or paid kickbacks to Medicare beneficiaries who were Arriva customers in the form of (i) “free” or “no cost” home blood glucose monitors (glucometers or meters), and (ii) the routine waiver or non-collection of beneficiary copayment obligations, and then (2) submitted or caused to be submitted false claims on behalf of those Arriva customers to Medicare that were tainted by those unlawful kickbacks. The false claims included initially tainted claims for payment submitted on behalf of Arriva customers to Medicare between April 1, 2010 and December 31, 2016 for diabetic testing supplies billed under Healthcare Common Procedure Coding System codes E0607, A4253, A4256, A4258, and A4259, as well as subsequently tainted claims for diabetic testing supplies submitted to Medicare on behalf of those same Arriva customers as much as one year after those Medicare beneficiaries became tainted by the offer or payment of kickbacks to them. The United States contends that these claims were false because

they resulted from and were tainted by the kickbacks described above and in the Amended Complaint. *See* 42 U.S.C. § 1320a-7b(g).

2. From March 1, 2009 when Arriva opened to December 31, 2016, the United States contends that the Arriva Defendants submitted or caused to be submitted false Arriva claims to Medicare for new glucometers for beneficiaries whom the Arriva Defendants knew had received a glucometer paid for by Medicare within the past five years, even though the new glucometers were for that reason not covered by Medicare under 42 U.S.C. § 1395m(a)(7)(C)(ii) and 42 C.F.R. § 414.210(f)(1).

3. From April 15, 2011 to April 25, 2016, the United States contends that Arriva submitted or caused to be submitted 227 false claims of Arriva to Medicare for 211 beneficiaries who had been deceased for more than fourteen days, as of Arriva's reported dates of service for the claims. The claims are specifically identified in Exhibit A to this Agreement.

The conduct described in Paragraph D is hereinafter referred to as the "Covered Conduct."

E. This Settlement Agreement is neither an admission of liability by the Arriva Defendants nor a concession by the United States that its claims are not well founded. The Arriva Defendants deny the United States' allegations in Paragraph D and the Relator's allegations in the Civil Action.

F. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. The Arriva Defendants shall pay to the United States \$160,000,000 (Settlement Amount), and interest on the Settlement Amount at a rate of 1.625% per annum from April 19, 2021, of which \$79,637,517 is restitution, no later than 14 days after the Effective Date of this Agreement, by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the Middle District of Tennessee.

2. Conditioned upon the United States receiving the Settlement Amount and as soon as feasible after receipt, the United States shall pay \$28,548,749 to Relator by electronic funds transfer (Relator's Share).

3. Subject to the exceptions in Paragraph 5 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount and applicable interest, the United States releases the Arriva Defendants together with their current and former parent corporations, including Abbott; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

4. Upon the United States' receipt of the Settlement Amount and applicable interest, Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns, releases all Arriva Defendants together with their current and former parent corporations and any former or current Arriva, Alere, or Abbott director, officer, or employee from all liability, claims, demands, actions, or causes of action whatsoever, whether known or unknown, direct or indirect, fixed or contingent,

in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common law, that Relator, his heirs, successors, attorneys, agents and assigns otherwise would have standing to bring as of the date of this Agreement, including any liability to Relator arising from or relating to the claims Relator asserted or could have asserted in the Civil Action, including any civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

5. Notwithstanding the releases given in Paragraph 3 and 4 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory or permissive exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due;

- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; and
- j. Any liability of defendants in the Civil Action other than the Arriva Defendants, namely Ted Albin and Grapevine Billing and Consulting Service, Inc. (Grapevine).

6. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the Relator's Share, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

7. Relator, for himself, and for his heirs, successors, attorneys, agents, and assigns, releases the Arriva Defendants, and their directors, officers, agents, and employees, from any liability to Relator arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs.

8. The Arriva Defendants waive and shall not assert any defenses the Arriva Defendants may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

9. The Arriva Defendants fully and finally release the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that the Arriva Defendants have asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct or the United States' investigation or prosecution thereof.

10. The Arriva Defendants fully and finally release the Relator and his heirs, successors, attorneys, agents, and assigns from all liability, claims (including attorneys' fees, costs and expenses of every kind), demands, actions, or causes of action whatsoever, whether known or unknown, direct or indirect, fixed or contingent, in law or in equity, in contract or in tort, under any federal or state statute or regulation, or in common law, that Defendants, their heirs, successors, current or former parent corporations, attorneys, agents and assigns otherwise would have standing to bring as of the date of this Agreement, including any liability that the Arriva Defendants have asserted, could have asserted, or may assert in the future against the Relator, related to the Covered Conduct and the Relator's investigation and prosecution thereof.

11. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and the Arriva Defendants agree not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agree not to appeal any such denials of claims, and agree to withdraw any such pending appeals.

12. The Arriva Defendants agree to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition

Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of the Arriva Defendants, their present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) The Arriva Defendants' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment the Arriva Defendants make to the United States pursuant to this Agreement and any payments that the Arriva Defendants may make to Relator, including costs and attorneys' fees;

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by the Arriva Defendants, and the Arriva Defendants shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by the Arriva

Defendants or any of their subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: the Arriva Defendants further agree that within 90 days of the Effective Date of this Agreement they shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by the Arriva Defendants or any of their subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. The Arriva Defendants agree that the United States, at a minimum, shall be entitled to recoup from the Arriva Defendants any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by the Arriva Defendants or any of their subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on the Arriva Defendants or any of their subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine the Arriva Defendants' books and records to

determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

13. The Arriva Defendants agree to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, the Arriva Defendants shall encourage, and agree not to impair, the cooperation of their directors, officers, and employees, and shall use their best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. The Arriva Defendants further agree to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in their possession, custody, or control concerning any investigation of the Covered Conduct that they have undertaken, or that has been performed by another on their behalf.

14. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraphs 3, 4, and 15 (waiver for beneficiaries paragraph), below. This includes other defendants to the Civil Action who are not party to this agreement, namely Albin and Grapevine.

15. The Arriva Defendants agree that they waive and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

16. Upon receipt of the payment described in Paragraph 1, above, the Parties shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action With Prejudice (Joint Stipulation) as to the Arriva Defendants as to all claims in the Civil Action against

them pursuant to Rule 41(a)(1). The Joint Stipulation shall not dismiss claims against other defendants in the Civil Action, specifically Albin and Grapevine.

17. The terms of any payments by the Arriva Defendants to Relator or Relator's counsel for attorney's fees, expenses and costs shall be made in accordance with a separate agreement between Relator and the Arriva Defendants. Except as may be set out in any such separate agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

18. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

19. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Middle District of Tennessee. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

20. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

21. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

22. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

23. This Agreement is binding on the Arriva Defendants' successors, transferees, heirs, and assigns.

24. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.


25. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

26. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA


DATED: 7/30/21

BY:


JAKE M. SHIELDS
Trial Attorney
Civil Division, Fraud Section
United States Department of Justice


DATED: 7/30/21

BY:


ELLEN BOWDEN MCINTYRE
Assistant United States Attorney
U.S. Attorney's Office for
the Middle District of Tennessee

DATED: 7/21/2021

BY:


LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

THE ARRIVA DEFENDANTS

DATED: 7/27/21

BY: _____

DAVID E. MENDELSON
Divisional Vice President and
Associate General Counsel Litigation
Abbott Laboratories on behalf of
Arriva Medical, LLC and Alere Inc.

DATED: 7/21/2021

BY: _____

ELIZABETH S. HESS
HENRY J. DEIPPO
Counsel for Arriva Medical, LLC and Alere Inc.

RELATOR

DATED: _____

BY: _____

GREGORY M. GOODMAN

DATED: _____

BY: _____

JERRY MARTIN
Barrett Johnston Martin & Garrison LLP
Counsel for Gregory M. Goodman

THE ARRIVA DEFENDANTS

DATED: _____

BY: _____

DAVID E. MENDELSON
Divisional Vice President and
Associate General Counsel Litigation
Abbott Laboratories on behalf of
Arriva Medical, LLC and Alere Inc.

DATED: _____

BY: _____

ELIZABETH S. HESS
HENRY J. DEPIPPA
Counsel for Arriva Medical, LLC and Alere Inc.

RELATOR


DATED: 7/21/2021

BY: _____


GREGORY M. GOODMAN

DATED: 7/21/2021

BY: _____


JERRY MARTIN
Barrett Johnston Martin & Garrison LLP
Counsel for Gregory M. Goodman